

510(K) SUMMARY

Subject 510(k) Number _____

AUG 15 2007

Sponsor

Core Essence Orthopaedics, LLC
301 Oxford Valley Road
Suite 905B
Yardley, PA 19067

FDA Establishment Registration Number

Pending

Official Contact

Shawn T. Huxel, CEO & President
Core Essence Orthopaedics, LLC
301 Oxford Valley Road
Suite 905B
Yardley, PA 19067
Phone - (215) 310-9534
Fax - (609) 482-4957
Mobile - (908) 896-5893

Proprietary Name

reVERTO™ Shape Memory Staples

Common Name

Staple, Fixation, Bone

Classification Name and Reference

Sec. 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class

Class II

Device Product Code

(Panel 87) JDR

Date Prepared

24 May, 2007

Brief Description of Device

reVERTO™ Shape Memory Staples are dynamic compression implants that use shape memory metal nickel-titanium alloy called NiTiNol (see below for more information on NiTiNol). The NiTiNol construction causes the legs of the implant to deflect, thereby creating a compressive force across the site of fixation. reVERTO Shape Memory Staples are advantageous to screws and plates in that they require less disruption of the surrounding bone for implantation and provide a 'low-profile' fixation. The most important factor related to the use of NiTiNol is its ability to maintain a compressive force across the site of fixation during the healing process.

Indications for Use

reVERTO™ Shape Memory Staples are intended for use in:

Fixation of Osteotomies of the Hand, Foot and Tibia

Arthrodesis of the Joints of the Hand and Foot

Fixation of Soft Tissue to Bone, as in the case of the Anterior Cruciate Ligament

reVERTO™ Shape Memory Staples are also indicated for adjunctive fixation of Small Bone Fragments of:

The Upper Extremity, such as the Radius, Ulna, Humerus, Clavicle and Scapula

The Lower Extremity, such as the Tibia, Fibula and the Femur

The Upper Torso, such as the Sternum and the Ribs

Basis for Substantial Equivalence

The substantial equivalence of the reVERTO Shape Memory Staples is based on the equivalence in intended use, materials, operational principals, and indications to:

DEVICE	Manufacturer	Trade Name
K993714	Biomedical Enterprises	Memograph
K001354	Biomedical Enterprises	OSStaple
K051408	Intelifuse	Stimulink
K060014	Intelifuse	Stimulink
K002695	Telos Medical	Memodyn Staples

END OF 510(K) SUMMARY



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Core Essence Orthopaedics, LLC
% Mr. Shawn T. Huxel
CEO and President
301 Oxford Valley Rd.
Suite 905B
Yardley, Pennsylvania 19067

AUG 15 2007

Re: K071477

Trade/Device Name: reVERTO™ 55 Shape Memory Staples and
reVERTO™ 37 Shape Memory Staples

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple component metallic bone fixation appliances
and accessorites

Regulatory Class: II

Product Code: JDR

Dated: July 17, 2007

Received: July 18, 2007

Dear Mr. Huxel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

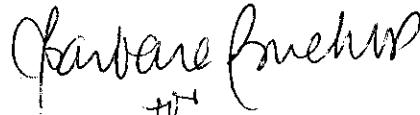
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CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) NUMBER IF KNOWN: K071477

DEVICE NAME: reVERTO™ Shape Memory Staples

Indications for Use:

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The Lower Extremity, such as the Tibia, Fibula and the Femur

The Upper Torso, such as the Sternum and the Ribs

Prescription Use ☒

AND/OR

Over-the-Counter Use ☐

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for NXM
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

Core Essence Orthopaedics, LLC

Confidential

510(k) Number K071477